K103392

DEC 17 2010

510(k) Summary

Inovo, Inc.

Date Prepared:	November 15, 2010
Submitter Information:	Inovo, Inc. 2975 S. Horseshoe Dr. Naples Fl. 34104
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Proprietary Names:	Chad Therapeutic Evolution Electronic Oxygen Conserver
Common Name:	Oxygen Conserver
Inovo Model Number	OM-900 Series
Classification Name:	Class II, 21 CFR 868.5905 Non Continuous Ventilator
Product Code:	NFB
Predicate Device Equivalence:	K042142 – Chad Therapeutic Lotus Models OM-700 & OM-700S

Device Description:

The Inovo Evolution is a microprocessor-controlled device, which is a combination of a oxygen pressure regulator and a oxygen conserver, designed for use with ambulatory oxygen systems. The built in oxygen regulator reduces the oxygen pressure from the oxygen cylinder to ensure proper operation of the oxygen conserving device. The low pressure oxygen enters the conserver portion of the device where the breath detection circuitry and inhalation sensors convert the low pressure oxygen to deliver a precise amount of supplemental oxygen at a specific point in the breathing cycle. It delivers boluses of oxygen that is equivalent to 1 to 7 liters per minute depending on the flow rate setting

Intended Use:

The Inovo Evolution is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen up to 7 liters per minute, in their home and for ambulatory use.

Comparison of Device Technological Characteristics to Predicate Devices:

The submitted Inovo Evolution OM-900 Series has the following similarities to the predicate OM-700 Series

- Has the same intended use
- Incorporates the same basic modes and settings
- Incorporates similar materials
- Oxygen delivery method is fundamentally equivalent

There is a technological characteristic difference between the Evolution and the predicate device. The breath detection circuitry and sensors utilized in the Evolution are new but are based on the same operating principles of the Lotus breath detection circuitry and sensor. The bolus sizes for the Evolution are the same with the exception of one additional setting No. 7.The software and electronics have been modified to extend battery life

Statement of Safety and Effectiveness

Analysis of comparison of design, function and features of the Inovo Evolution OM-900 Series to the (K042142) Lotus OM-700, OM700S Series Electronic Conserver, together with the results of testing demonstrates the device to be substantially equivalent to the predicate device in terms of meeting performances criteria and functioning as intended.

Conclusion

Based on the above, we conclude that the Inovo Evolution OM-900 Series Electronic Conserver is substantially equivalent to the predicate device listed and does not raise any new issues of safety and effectiveness. .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Mr. Michael T. Dildine
Director, Quality Assurance
Inovo, Incorporated
2975 S. Horseshoe Drive, Suite 600
Naples, Florida 34104

Re: K103392
Trade/Device Name: Chad Therapeutics Evolution Model OM-900
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: November 15, 2010
Received: November 19, 2010

Dear Mr. Dildine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Chad Therapeutics Evolution Model OM-900

Indications for Use:

The Chad Therapeutics Evolution Model OM-900 is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen up to 7 liters per minute, in their home and for ambulatory use

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of ~~Device~~ Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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